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April 6, 1989

Clifford W. Browning
Woodward, Emhardt, Naughton,
Moriarty & McNett
One Indiana Square
Suite 2000
Indianapolis, Indiana 46204

#31

RE: Patent Term Extension
Application for
U.S. Patent No. 4,543,956
Issued: October 1, 1985

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,543,956, issued October 1, 1985, is eligible for patent term extension under 35 USC 156. The period of extension has been determined to be 410 days.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of August 26, 1988 as follows:

$$\begin{aligned}\text{Period} &= 1/2 \text{ (Testing Phase)} + \text{Approval Phase} \\ &= 1/2 (572) + 124 \\ &= 410 \text{ days}\end{aligned}$$

Since the regulatory review period took place after the patent issue date and there was no determination of a lack of due diligence, the entire period has been considered. The exception of 35 USC 156 (c) (3) does not operate to reduce the period determined above.

A single request for reconsideration of this final determination as to eligibility and the length of extension of the term of U.S. Patent 4,543,956 may be made if filed within one (1) month of the date of this notice. This period is not subject to the provisions of 37 CFR 1.136(a). In the absence of such request, the Commissioner will issue to the applicant for extension of the term of Patent No. 4,543,956, a certificate of extension, under seal, for a period of 410 days. The rights derived from the patent during the period during which the patent is extended are defined in 35 USC 156(b).

Upon issuance of the certificate of extension the following information will be published in the Official Gazette:

U.S. Patent No. 4,543,956, granted October 1, 1985 to
William A. Cook et al
Owner of Record: Purdue Research Foundation
Title: EXERCISE RESPONSIVE CARDIAC PACEMAKER
Classification: 128-419 PG
Product Trade Name: Sensor Model Kelvin 500
Term Extended: 410 days

C. E. Van Horn

Charles E. Van Horn
Deputy Solicitor
Patent and Trademark Office

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

RE: Sensor Model
Kelvin 500
FDA Docket # 88E-0269